



PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/758,242		
		Filing Date	January 16, 2004		
		First Named Inventor	Bernd SUNDERMANN		
		Art Unit	1621		
		Examiner Name	Unassigned		
Sheet	1	of	5	Attorney Docket Number	029310.53093US

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)				
BJD	AA	US- 5,304,479		04-19-1994	Cheng-I Lin	
BJD	AB	US- 5,239,110		08-24-1993	John P. Mallamo et al.	
BJD	AC	US- 4,366,172		12-28-1982	Daniel Lednicer	
BJD	AD	US- 4,346,101		08-24-1982	Daniel Lednicer	
BJD	AE	US- 4,212,878		07-15-1980	Daniel Lednicer et al.	
BJD	AF	US- 4,115,589		09-19-1978	Daniel Lednicer	

FOREIGN PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
B JD	AG	DE 2839891	04-12-1979	The Upjohn Co.		AB
R JD	AH	DE 19963175	07-12-2001	Gruenthal GmbH		AB
P JD	AI	WO 01/12195	02-22-2001	Gruenthal GmbH		AB
B JD	AJ	EP 0410191	01-30-1991	Bayer AG		AB

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
BJD	AK	DANIEL LEDNICER ET AL., "4-(p-Bromophenyl)-4-(dimethylamino)-1-phenethylcyclohexanol, an Extremely Potent Representative of a New Analgesic Series", Journal of Medicinal Chemistry, October 1979, pp. 1157-1158, Vol. 22, No. 10, American Chemical Society	
BJD	AL	HIROSHI KAWAMOTO ET AL., "Synthesis of J-113397, the First Potent and Selective ORL1 Antagonist," Tetrahedron, 2001, pp. 981-986, 57, Elsevier Science Ltd.	
	AM	PHILLIP F. VONVOIGTLANDER ET AL., "4-Aryl-4-aminocyclohexanones Derivatives: A Chemical Novel Series of Analgesics Including Opioid Antagonist and Extremely Potent Agent," pp. 17-24	

Examiner Signature		Date Considered	12/27/05
--------------------	--	-----------------	----------


*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/758,242		
		Filing Date	January 16, 2004		
		First Named Inventor	Bernd SUNDERMANN		
		Art Unit	1621		
		Examiner Name	Unassigned		
Sheet	2	of	5	Attorney Docket Number	029310.53093US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
BSD	AN	FAUD A. ABDULLA ET AL., "Axotomy Reduces the Effect of Analgesic Opioids Yet Increases the Effect of Nociceptin on Dorsal Root Ganglion Neurons," The Journal of Neuroscience, December 1, 1998, pp. 9685-9694, 18, 23, Society for Neuroscience		
BSD	AO	GIROLAMO CALO ET AL., "Pharmacology of Nociceptin and its Receptor: A Novel Therapeutic Target," British Journal of Pharmacology, 2000, pp. 1261-1283, 129, Macmillan Publishers Ltd.		
BSD	AP	MARK CONNER ET AL., "The Effect of Nociceptin on Ca ²⁺ Channel Current and Intracellular Ca ²⁺ in the SH-SY5Y Human Neuroblastoma Cell Line", 1996, pp. 205-207, 118, Stockton Press		
BSD	AQ	E.S.L. FABER ET AL., "Depression of Glutamatergic Transmission by Nociceptin in the Neonatal Rat Hemisectioned Spinal Cord Preparation <i>In Vitro</i> ", Special Report, July 19, 1996, pp. 1-2,		
BSD	AR	"Opioid and Opiate Receptors: Peptides and Knock-Out," Society for Neuroscience, 1998, p. 1358, Vol. 24		
BSD	AS	FRANCOIS JENCK ET AL., "Orphanin FQ Acts as an Anxiolytic to Attenuate Behavioral Responses to Stress," Proc. Natl. Acad. Sci., December 1997, pp. 14854-14858, Vol. 94, USA		
BSD	AT	MICHAEL A. KING ET AL., "Spinal Analgesic Activity of Orphanin FQ/Nociceptin and its Fragments", Neuroscience Letters, 1997, pp. 113-116, 223, Elsevier Science Ireland Ltd.		
BSD	AU	TOSHIYA MANABE ET AL., "Facilitation of Long-Term Potentiation and Memory in Mice Lacking Nociceptin Receptors", Letters To Nature, August 6, 1998, pp. 577-581, Vol. 394, Macmillan Publishers Ltd.		
BSD	AV	JEAN-CLAUDE MEUNIER ET AL., "Isolation and Structure of the Endogenous Agonist of Opioid Receptor-Like ORL ₁ Receptor," Letters to Nature, October 12, 1995, pp. 532-535, Vol. 377		
Examiner Signature			Date Considered	12/27/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

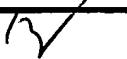
This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known			
		Application Number	10/758,242		
		Filing Date	January 16, 2004		
		First Named Inventor	Bernd SUNDERMANN		
		Art Unit	1621		
		Examiner Name	Unassigned		
Sheet	3	of	5	Attorney Docket Number	029310.53093US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
BJD	AW	J.S. MOGIL ET AL., "Orphanin FQ is a Functional Anti-Opioid Peptide", Neuroscience, 1996, pp. 333-337, Vol. 75, No. 2, Elsevier Science Ltd., Great Britain	
BJD	AX	MIYUKI NISHI ET AL., "Unrestrained Nociceptive Response and Disregulation of Hearing Ability in Mice Lacking the Nociceptin/OrphaninFQ Receptor," The EMBO Journal, 1997, pp. 1858-1864, Vol. 16, No. 8, Oxford University Press	
BJD	AY	RAINER K. REINSCHIED ET AL., "Orphanin FQ: A Neuropeptide That Activates an Opioidlike G Protein-Coupled Receptor," Science, November 3, 1995, pp. 792-794, Vol. 270	
BJD	AZ	CHRISTOPHER W. VAUGHAN ET AL., "Increase by the ORL ₁ Receptor (Opioid Receptor-like ₁) Ligand, Nociceptin, of Inwardly Rectifying K Conductance in Dorsal Raphe Nucleus Neurones," Special Report, pp. 1609-1611	
BJD	BA	TATSUO YAMAMOTO ET AL., "Effects of Intrathecally Administered Nociceptin, an Opioid Receptor-like ₁ Receptor Agonist, and N-methyl-D-aspartate Receptor Antagonist on the Thermal Hyperalgesia Induced by Partial Sciatic Nerve Injury in the Rat," Anesthesiology, 1997, pp. 1145-1152, Vol. 87, No. 5, Lippincott-Raven Publishers	
BJD	BB	ALI ARDATI ET AL., "Interaction of [³ H]Orphanin FQ and [¹²⁵ I]-Tyr ¹⁴ -Orphanin FQ with the Orphanin FQ Receptor: Kinetics and Modulation by Cations and Guanine Nucleotides," Molecular Pharmacology, 1997, pp. 816-824, 51, The American Society for Pharmacology and Experimental Therapeutics	
BJD	BC	HUNTER C. CHAMPION ET AL., "[Tyr ¹]-Nociceptin, a Novel Nociceptin Analog, Decreases Systemic Arterial Pressure by a Naloxone-Insensitive Mechanism in the Rat," Biochemical and Biophysical Research Communications, 1997, pp. 309-312, 234, Academic Press	
BJD	BD	TRISTAN DARLAND ET AL., "Orphanin FQ/nociceptin: a Role in Pain and Analgesia, But So Much More," TINS, 1998, PP. 215-221, Vol. 21, No. 5, Elsevier Science Ltd.	

Examiner Signature		Date Considered	12/27/05
--------------------	---	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10758,242		
		Filing Date	January 16, 2004		
		First Named Inventor	Bernd SUNDERMANN		
		Art Unit	1621		
		Examiner Name	Unassigned		
Sheet	4	of	5	Attorney Docket Number	029310.53093US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
B JB	BE	BULENT GUMUSEL ET AL., "Nociceptin: An Endogenous Agonist for Central Opioid Like ₁ (ORL ₁) Receptors Possesses Systemic Vasorelaxant Properties," Life Sciences, 1997, pp. PL 141-145, Vol. 60, No. 8, Elsevier Science Inc., USA	
B JD	BF	NAOKI HARA ET AL., "Characterization of Nociceptin Hyperalgesia and Allodynia in Conscious Mice," British Journal of Pharmacology, 1997, pp. 401-408, 121, Stockton Press	
B SD	BG	DANIEL R. KAPUSTA ET AL., "Diuretic and Antinatriuretic Responses Produced by the Endogenous Opioid-Like Peptide, Nociceptin (Orphanin FQ)," Life Sciences, 1997, pp. PL 15-21, Vol. 60, No. 1, Elsevier Science Inc., USA	
B JD	BH	FREDERIC KNOFLACH ET AL., "Modulation of Voltage-Gated Calcium Channels by Orphanin FQ in Freshly Dissociated Hippocampal Neurons," The Journal of Neuroscience, November 1, 1996, pp. 6657-6664, 16, 21, Society for Neuroscience	
B SD	BI	HANS MATTHES ET AL., "Functional Selectivity of Orphanin FQ for Its Receptor Coexpressed with Potassium Channel Subunits in <i>Xenopus laevis</i> Oocytes," Molecular Pharmacology, 1996, pp. 447-450, 50, The American Society for Pharmacology and Experimental Therapeutics	
B JB	BJ	JEFFREY S. MOGIL ET AL., "Functional Antagonism of μ -, δ - and κ -opioid Antinociception by Orphanin FQ," Neuroscience Letters, 1996, pp. 131-134, 214, Elsevier Science Ireland Ltd.	
B JB	BK	CATHERINE MOLLEREAU ET AL., "ORL1, A Novel Members of the Opioids Receptor Family Cloning, Functional Expression and Localization," FEBS Letters, 1994, 341, Federation of European Biochemical Societies	
B SD	BL	JAMES D. POMONIS ET AL., "Orphanin FQ, Agonist of Orphan Opioid Receptor ORL ₁ , Stimulates Feeding in Rats," NeuroReport, December 20, 1996, pp. 369-371, Vol. 8, No.1, Rapid Science Publishers	

Examiner Signature		Date Considered	12/27/05
--------------------	---	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete If Known			
		Application Number	10/758,242		
		Filing Date	January 16, 2004		
		First Named Inventor	Bernd SUNDERMANN		
		Art Unit	1621		
		Examiner Name	Unassigned		
Sheet	5	of	5	Attorney Docket Number	029310.53093US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
B JD	BM	Y.-S. SHU ET AL., "Orphanin FQ/Nociceptin Modulates Glutamate- and Kainic Acid-Induced Currents in Acutely Isolated Rat Spinal Dorsal Horn Neurons," Neuropeptides, 1998, pp. 567-571, 32, Harcourt Brace & Co., Ltd.	
B JD	BN	XIAO-JUN XU ET AL., "Nociceptin or Antinociceptin: Potent Spinal Antinociceptive Effect of Orphanin FQ/ Nociceptin in the Rat," NeuroReport, September 2 1996, Vol. 17, No. 13, Rapid Science Publishers	
B JD	BO	T. YAMAMOTO ET AL., "Analgesic Effect of Intrathecally Administered Nociceptin, an Opioid Receptor-Like, Receptor Agonist, in the Rat Formalin Test," Neuroscience, 1997, pp. 249-254, Vol. 81, Elsevier Science Ltd.	
B JD	BP	M.N.A. RAO ET AL., "Quantitative Correlation Between Hydrophobicity and Analgesis Activity of 4-Amino 4-Arylcyclohexanols," Indian Drugs, 1985, pp. 252-257, 22, 5	
B JD	BQ	JEAN-MARC KAMENKA ET AL., "Orientation Structurale et Conformationnelle de la Fixation de la Phencyclidine dans le SNC," Eur. J. Med. Chem. 1984, pp. 255-260, 19, 3	
B JD	BR	DANIEL LEDNICER ET AL., "4-Amino-4-arylcyclohexanones and Their Derivatives, a Novel Class of Analgesics", J. Med. Chem., 1980, pp. 424-430, 23	

Examiner Signature		Date Considered	12/27/05
--------------------	---	-----------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.